

Industry Survey of SPL Business Process

1. Industry Survey of SPL Business Processes

Dear Industry Member,

The SPL Working Group is conducting a survey of industry plans to implement business processes to support electronic submission of Drug Establishment Registration and Drug Product Listing in SPL format. Your participation in this survey would be greatly appreciated.

- This survey is applicable for Drug Establishment Registration and Drug Product Listing submissions made to CBER, CDER, and CVM.
- Your participation is anonymous. Your company name and your email address will only be used to collate and clarify answers if necessary and will not be made public.
- You do not need to be a member of the SPL Working Group to participate in the survey.
- The survey is conducted online. It will take approximately 10-15 minutes to complete.
- Blinded, collective survey results will be posted to the SPL Working Group Wiki site.
- FDA is NOT, in any way, involved in the preparation of this survey or the subsequent data collection effort. The results from this survey will not be provided to the FDA. FDA employees will not utilize the information collected from this survey in presentations or documentation related to the electronic drug registration and drug listing initiative or the Structured Product Labeling standard.

Please press *next* to begin the survey.

Thank you for your participation,

SPL Working Group WIKI Survey Team

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2. Identification for Aggregation Purposes


1. In order to accurately combine multiple surveys coming from your corporation, we would like to know your corporate name. Your corporate name is not used for any other purpose and will not be made public.

Corporate Name:

2. You may not be familiar with the electronic SPL submission plans at the corporate level. If you are answering this survey for a particular business group, we need to collate the various group responses for your corporation.

I am responding for:

 My entire corporation (e.g., your organization has three business units that handle medicinal products and you are answering for all of them)


 Only a group (e.g., your organization has multiple units/divisions covering Human Pharmaceutical, Human Biologic/Vaccine, Animal Health and Over-the-Counter/Consumer HealthCare and you are answering for only one or a few groups)

Group/Unit Name(s):

* 3. We will be periodically tabulating the results from this survey. You can fill the survey out more than once between now and the FDA's implementation date for eListing (currently targeted for June 1, 2009)

Is this the first time you are filling out this survey?

4. If you are not familiar with your company's NDC Labeler Codes and how they are maintained, please choose SKIP and click on NEXT which will skip you to the Establishment Registration section.

 Continue

 SKIP

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3. NDC Labeler Code

Note: the NDC Labeler Code is the first 4-5 number segment of the full NDC code, e.g., 1234-1234-12.

5. How many active NDC Labeler Codes does your corporation/business unit have?

6. How do you currently store your NDC Labeler Code submission documents (Form 2656)?

☐ Electronic (e.g., MS Word, PDF)

☐ Paper

☐ Other/I don't know, please provide details

7. How do you currently store your NDC Labeler Code data?

☐ One or more database or document management system(s) (e.g. ORACLE or SQLServer database, SAP resource management system, Documentum doctype)

☐ Other electronic format (e.g., spreadsheet, Word or text document)

☐ Paper

☐ Other, please provide details:

8. Who currently submits Labeler Code Requests?

☐ Regulatory Product Listing person

☐ Regulatory Product Labeling person

☐ Other/I don't know, please provide details:

9. In the future, who will submit electronic Labeler Code Requests in SPL?

☐ Regulatory Product Listing person

☐ Regulatory Product Labeling person

☐ Other/I don't know, please provide details:

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4. NDC Labeler Code (continued)

10. Do you know what a D-U-N-S Number is?

11. Do you know the D-U-N-S Number for each Labeler site?

☐ Yes, all sites

☐ Yes, >75% of sites

☐ Yes, approx 50% of sites

☐ Yes, <25% of sites

☐ No, none

12. Do you need to request any D-U-N-S numbers?

☐ Yes, all sites

☐ Yes, >75% of sites

☐ Yes, approx 50% of sites

☐ Yes, <25% of sites

☐ No, none

13. How do you plan to identify (or how did you identify) your Labeler D-U-N-S Number(s)?

☐ Check with internal corporate financial personnel

☐ Go directly to the Dun and Bradstreet website

☐ Use a third party source for assistance

☐ No plans yet

☐ Other, please provide details

14. If you are not familiar with your company's Establishment Registrations (Form 2656) and how they are maintained, please skip to the Product Listing section.

☐ SKIP

☐ Continue

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5. Establishment Registration

15. How many active Establishment sites does your corporation/business unit have?

Number of U.S. Establishments

Number of Foreign Establishments

16. Are your Establishment Registrations currently sent from one or many location (s)?

☐ Submissions are made by individuals at each site

☐ Submissions are made by a single person/group on behalf of many sites

☐ Other, please provide details:

17. How do you currently store your Establishment Registration submission documents (Form 2656)?

☐ Electronic (e.g., MS Word, PDF)

☐ Paper

☐ Other/I don't know, please provide details:

18. How do you currently store your Establishment Registration submission data?

☐ One or more database or document management system(s) (e.g. ORACLE or SQLServer database, SAP resource management system, Documentum docbase)

☐ Other electronic format (e.g., spreadsheet, text document)

☐ Paper

☐ Other, please provide details:

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6. Establishment Registration (cont.)

19. Who currently submits Establishment Registrations for your corporate/business unit?

☐ Establishment Registration and/or Product Listing person within a Regulatory Affairs group/department

☐ Product Labeling person within a Regulatory Affairs group/department

☐ Establishment Registration and/or Product Listing person within a Manufacturing group/department

☐ Other, please provide details:

20. Who (in the future) will submit electronic Establishment Registrations in SPL?

☐ Establishment Registration and/or Product Listing person within a Regulatory Affairs group/department

☐ Product Labeling person within a Regulatory Affairs group/department

☐ Establishment Registration and/or Product Listing person within a Manufacturing group/department

☐ Other, please provide details:

21. Have you identified your Registrant site and all your Establishment sites?

☐ Yes, all sites

☐ Yes, >75% of sites

☐ Yes, approx 50% of sites

☐ Yes, <25% of sites

☐ No, none

22. If you have foreign Establishment sites, have you identified your U.S. Agent and Importer(s) for each site?

23. Do you know your D-U-N-S Number(s) assigned to each Registrant and Establishment site?

☐ Yes, all sites

☐ Yes, >75% of sites

☐ Yes, approx 50% of sites

☐ Yes, <25% of sites

☐ No, none

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24. How do you plan to identify (or how did you identify) your Registrant and Establishment site D U N S Number(s)?

- ☐ Check with internal corporate financial personnel
- ☐ Go directly to the Dun and Bradstreet website
- ☐ Use a third party source for assistance
- ☐ No plans yet
- ☐ Other, please provide details

25. If you are not familiar with your company's Product Listings (Form 2657, 2658) and how they are maintained, please skip to the FDA eDRL Pilot Program section.

☐ SKIP

☐ Continue

7. Product Listing

26. Number of Products by Type:
Count only active NDC Product Codes. The Product Code includes the first and second segment of the full NDC code, e.g., 1234-1234-12.

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>

Center--Product Type

	Approx number of products	Brand/Generic
CDER - Prescription	<input type="text"/>	<input type="text"/>
CDER - OTC (Over-the-Counter)	<input type="text"/>	<input type="text"/>
CDER - API (Active Pharmaceutical Ingredient)	<input type="text"/>	<input type="text"/>
CDER - Biologic	<input type="text"/>	<input type="text"/>
CDER - Biologic including Vaccines	<input type="text"/>	<input type="text"/>
CVM - Prescription	<input type="text"/>	<input type="text"/>
CVM - VFD (Veterinary Feed Directive)	<input type="text"/>	<input type="text"/>
CVM - OTC	<input type="text"/>	<input type="text"/>

27. How do you currently store your Product Listing submission documents?

☐ Electronic (e.g., MS Word, PDF)

☐ Paper

☐ Other/I don't know, please provide details:

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8. Product Listing (continued)

28. How do you currently store your Product Listing data?

- ☐ One or more database or document management system(s) (e.g. ORACLE or SQLServer database, SAP resource management system, Documentum doabase)
- ☐ Other electronic format (e.g., spreadsheet, text document)
- ☐ Paper
- ☐ Other, please provide details:

29. Who currently submits Product Listings for your corporate/business unit?

- ☐ Establishment Registration and/or Product Listing person within a Regulatory Affairs group/department
- ☐ Product Labeling person within a Regulatory Affairs group/department
- ☐ Establishment Registration and/or Product Listing person within a Manufacturing group/department
- ☐ Other, please provide details:

30. Who (in the future) will submit electronic Product Listing(s) in SPL?

- ☐ Establishment Registration and/or Product Listing person within a Regulatory Affairs group/department
- ☐ Product Labeling person within a Regulatory Affairs group/department
- ☐ Establishment Registration and/or Product Listing person within a Manufacturing group/department
- ☐ Other, please provide details:

31. Have you identified the Labeler, Registrant (if necessary) and the Establishment site(s) for each product?

- ☐ Yes, all sites
- ☐ Yes, > 75% of sites
- ☐ Yes, approx 50% of sites
- ☐ Yes, < 25% of sites
- ☐ No, none

32. If you are not familiar with the FDA's electronic Drug Registration and Listing (eDRL) Pilot Program, please skip to the FDA Electronic Submission Gateway (ESG) section.

- ☐ SKIP
- ☐ Continue

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9. FDA eDRL Pilot Program

33. How did you hear about the FDA eDRL Pilot Program (choose as many as needed)?

- ☐ Federal Register Notice
- ☐ Reading the Draft Guidance
- ☐ Communication from Colleague inside your organization
- ☐ Communication from Colleague outside your organization
- ☐ Educational/training session provided by FDA
- ☐ Educational/training session provided by group other than FDA
- ☐ SPL Working Group WIKI
- ☐ Other, please provide details:

34. Do you plan to participate in the FDA eDRL Pilot Program?

35. If yes, please complete the following questions

	MM	DD	YYYY
Expected date of first Labeler Code Request SPL submission	<input type="text"/>	<input type="text"/>	<input type="text"/>
Expected date of first Establishment Registration SPL submission	<input type="text"/>	<input type="text"/>	<input type="text"/>
Expected date of first Product Listing/Content of Labeling SPL submission	<input type="text"/>	<input type="text"/>	<input type="text"/>

36. If you are not planning to participate in the FDA eDRL Pilot Program, please indicate why?

- ☐ Won't have software tool(s) or outsourced solution in place before June 1, 2009
- ☐ My company doesn't participate in pilot projects
- ☐ My company does not file labeler codes, establishment registrations or drug listings
- ☐ Other, please provide details:

37. Have you already participated in the FDA eDRL Pilot Program?

Number of Labeler Code Request SPL submissions	<input type="text"/>
Number of Establishment Registration SPL submissions	<input type="text"/>
Number of Product Listing/Content of Labeling SPL submissions	<input type="text"/>

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38. If you are not familiar with the FDA's Electronic Submission Gateway (ESG), please skip to the Company Organization section

 SKIP

 Continue

10. FDA Electronic Submission Gateway (ESG)

39. How do you plan to send your submission to the FDA?

- ☐ Use an existing ESG account(s)
- ☐ Create a dedicated ESG account(s) just for eList
- ☐ Use a third party
- ☐ No plans yet
- ☐ Other, please provide details:

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11. Company Organization

40. Select the best description of the labeling and listing activities within your corporation/business group:

- ☐ Combined Regulatory Product Listing and Labeling group
- ☐ Separate Regulatory Product Listing and Labeling groups, The groups are in the same building
- ☐ Separate Regulatory Product Listing and Labeling groups, The groups are in separate buildings on the same site
- ☐ Separate Regulatory Product Listing and Labeling groups, The groups are on different sites
- ☐ Other, please provide details:

41. How do you expect your organization's structure will change to effectively meet the FDA electronic submission requirement?

- ☐ No change
- ☐ Hire more people for current process
- ☐ Change lines of communication
- ☐ Reorganize department reporting structure
- ☐ No plans yet
- ☐ Other, please provide details:

42. How does your corporation/business unit currently prepare electronic SPL submissions?

- ☐ Use a commercial off-the-shelf or configured software tool
- ☐ Use a customized software tool/system provided by one or more outside vendors
- ☐ Use an outsourced service
- ☐ Use an internally created system
- ☐ Don't currently prepare electronic SPL submissions
- ☐ Other, please provide details:

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43. How do you expect your corporation/business unit will prepare your future electronic SPL submissions?

- ☐ Make no change to our existing SPL solution
- ☐ Add new users/business units to an existing SPL solution (e.g. Human Health SPL system)
- ☐ Purchase a software tool
- ☐ Use an outsourced service
- ☐ Create/use an internal system
- ☐ No plans yet
- ☐ Other, please provide details:

12. Reference Only

44. Optional: Email address in case we need to contact you to clarify any answers.
Your email address will not be used for any other purpose.

Contact Email:

45. How did you hear about this survey?

- ☐ SPL Working Group WIKI
- ☐ SPL Working Group or Subteam meeting
- ☐ Colleague inside my organization
- ☐ Colleague outside my organization
- ☐ Educational/training session
- ☐ Other, please provide details: